



JC06 Rec'd PCT/PTO 12 MAY 2005

Atty. Dkt. No. 074129-0519

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Kazuhiro SAITO et al

Title: SUSTAINED-RELEASE PREPARATIONS

Appl. No.: 10/530,186

Filing Date: 04/04/2005

Examiner: Unassigned

Art Unit: Unassigned

2

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56.

A copy of each non-U.S. patent document and each non-patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), within three (3) months of the date of entry of the national stage as set forth in 37 CFR §1.491.

RELEVANCE OF EACH DOCUMENT

An English translation of the foreign-language documents is not readily available. However, English language abstracts are provided herewith. Consequently, the foreign language documents have been submitted in compliance with the PTO requirements and, therefore, the documents should be considered by the Examiner (37 CFR §1.97, §1.98 and MPEP §609).

Applicants respectfully request that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

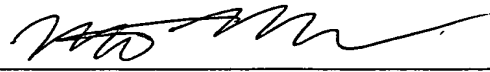
The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

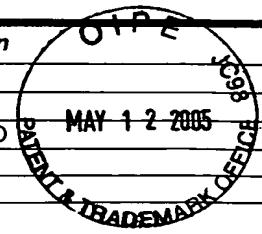
Date May 12, 2005

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5490
Facsimile: (202) 672-5399

By


fd Michael D. Kaminski *Matthew Mulkeen*
Attorney for Applicant
Registration No. 32,904 *Reg No 44,250*

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: May 12, 2005 <i>(use as many sheets as necessary)</i>				Complete if Known Application Number: 10/530,186 Filing Date: 04/04/2005 First Named Inventor: Kazuhiro SAITO Group Art Unit: Unassigned Examiner Name: Unassigned Attorney Docket Number: 074129-0519	
Sheet	1	of	2		



U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
	A1	4,652,441		Okada et al.	03/24/1987	
	A2	4,711,782		Okada et al.	12/08/1987	
	A3	4,728,721		Yamamoto et al.	03/01/1988	
	A4	4,849,228		Yamamoto et al.	07/18/1989	
	A5	4,917,893		Okada et al.	04/17/1990	
	A6	4,954,298		Yamamoto et al.	09/04/1990	
	A7	5,061,492		Okada et al.	10/29/1991	
	A8	5,330,767		Yamamoto et al.	07/19/1994	
	A9	5,476,663		Okada et al.	12/19/1995	
	A10	5,575,987		Kamei et al.	11/19/1996	
	A11	5,585,460		Yamada et al.	12/17/1996	
	A12	5,611,971		Maedara et al.	03/18/1997	
	A13	5,631,020		Okada et al.	05/20/1997	
	A14	5,631,021		Okada et al.	05/20/1997	
	A15	5,716,640		Kamei et al.	02/10/1998	
	A16	5,851,451		Takechi et al.	12/22/1998	
	A17	6,036,976		Takechi et al.	03/14/2000	
	A18	6,045,830		Igari et al.	04/04/2000	
	A19	6,113,943		Okada et al.	09/05/2000	
	A20	6,190,700	B1	Okada et al.	02/20/2001	
	A21	6,419,961	B1	Igari et al.	07/16/2002	
	A22	6,506,410	B1	Park et al.	01/14/2003	
	A23	6,699,500	B2	Okada et al.	03/02/2004	
	A24	6,740,634	B1	Saikawa et al.	05/25/2004	

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵ (if known)				
	A25	EP	1 197 208	A1	Takeda Chemical Industries, Ltd.	04/17/2002		
	A26	EP	1 330 293		Takeda Chemical Industries, Ltd.	07/30/2003	Corresponds to WO 03/002092	Abs
	A27	EP	1 399 133		Takeda Chemical Industries, Ltd.	03/24/2004	Corresponds to WO 03/002091	Abs
	A28	EP	1 466 596	A1	Takeda Chemical Industries, Ltd.	10/13/2004		
	A29	JP	63-267720		Morishita Pharma	11/04/1988		Abs
	A30	JP	4-321622		Takeda Chemical Industries, Ltd.	11/11/1992		Abs
	A31	JP	9-500645			01/21/1997		Abs
	A32	JP	10-231242		Taiyo Pharma Ind.	09/02/1998		Abs

Examiner Signature	Date Considered	
--------------------	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

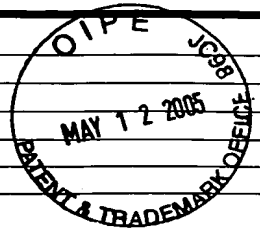
¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: May 12, 2005 <i>(use as many sheets as necessary)</i>				Complete if Known <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">Application Number</td> <td>10/530,186</td> </tr> <tr> <td>Filing Date</td> <td>04/04/2005</td> </tr> <tr> <td>First Named Inventor</td> <td>Kazuhiro SAITO</td> </tr> <tr> <td>Group Art Unit</td> <td>Unassigned</td> </tr> <tr> <td>Examiner Name</td> <td>Unassigned</td> </tr> <tr> <td>Attorney Docket Number</td> <td>074129-0519</td> </tr> </table>		Application Number	10/530,186	Filing Date	04/04/2005	First Named Inventor	Kazuhiro SAITO	Group Art Unit	Unassigned	Examiner Name	Unassigned	Attorney Docket Number	074129-0519
Application Number	10/530,186																
Filing Date	04/04/2005																
First Named Inventor	Kazuhiro SAITO																
Group Art Unit	Unassigned																
Examiner Name	Unassigned																
Attorney Docket Number	074129-0519																
Sheet	2	of	2														



FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵ (if known)				
	A33	JP	2003-206240		Takeda Chemical Industries, Ltd.	07/22/2003		Abs
	A34	PCT	WO 00/40259		Dong Kook Pharmaceutical Co., Ltd.	07/13/2000		
	A35	PCT	WO 01/74392	A1	Tanabe Seiyaku Co., Ltd.	10/11/2001		Abs
	A36	PCT	WO 2004/000363	A1	Takeda Chemical Industries, Ltd.	12/31/2003		Abs

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	A37	CHOI, Seung Ho et al., "Hydrophobic ion pair formation between leuprolide and sodium oleate for sustained release from biodegradable polymeric microspheres", <i>INTERNATIONAL JOURNAL OF PHARMACEUTICS</i> , Vol. 203, (2000), pgs. 193-202.	
	A38	Korean Drug Insert, "LH-RH Derivative for Monthly Adminstration, Rorelin Depot Injection (leuprorelin acetate 3.75 mg)", (Sold by Hanmi Corporation; prepared on March 13, 2000, revised on August 13, 2002) with its partial English translation.	

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.